

## REMARKS

### I. INTRODUCTION

With this RCE and Submission, Applicants submit the fee and petition for two months extension of time. Grant of this petition is hereby solicited.

As set forth above, claims 9, 10, 26 and 27 have been previously cancelled, and claims 1-4, 7, 18-21, 24, 34-37, and 47-28 are amended. Claims 1-8, 11-25, and 28-55 remain pending in the present application.

### II. CLAIM REJECTIONS UNDER 35 U.S.C. §103(A)

Claims 1-8, 11-25, 28-46 and 48-55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. US2003/0208454 by Rienhoff in view of U.S. Patent Application Publication No. US2003/0110058 by Fagan; and Claim 47 is rejected as being unpatentable over Rienhoff in view of U.S. Patent Application Publication No. US2002/0099796 by Chou. However, for a number of reasons, Applicants respectfully disagree with the Examiner's conclusions in Sections 57-58 of the aforementioned Office Action and submit that the teachings in the cited references do not support these claim rejections, singly or in combination.

Specifically, the claimed invention as recited in the independent claims 1, 18, 34-37, 47 and 48, involves, for instance, a database that, among other things, maintains event data. Claim 1 recites this aspect as follows: "a database... populated with study information... including... event data ..." Claim 18 recites this aspect as follows: "storing in a database study information ... which includes user data and study data..., wherein the study data includes... event data ..." Claim 34 recites this aspect as follows: "a database...operable to store ... study data includes... event data..." Claim 35 recites this aspect as follows: "a database... operable to store... study data includes... event data ..." Claim 36 recites this aspect as follows: "a database... populated with study information ... includes event data..." Claim 37 recites this aspect as follows: "database... and data access means operable to access information that resides in the database, the database being operable to store... study data... includes... event data..." Claim 47 recites this aspect as follows: "a data tier including a database and database management portion, wherein the database is configured for storing ... study data including ... event data..." Lastly, claim 48 recites this aspect as follows: "storing

datasets in a database..., the database being configured for maintaining clinical study data including... event data...”

One advantage derived from maintaining event data in the database is the ability to track events and monitor the progress of a clinical study (See, Applicants’ original disclosure, e.g., at paragraphs 184-186, 190 in page 22 and at paragraphs 233-236 in page 31). In hindsight, it would have made sense to include event data in connection with clinical study data management, but it is the claimed invention as recited in the above-enumerated independent claims that includes this feature.

The Examiner suggest that Rienhoff teaches a database operable to store event data (See, Office Action, e.g., Section 5 pages 3-4). However, Applicants respectfully disagree. Rienhoff does not teach event data stored in a database, let alone storing in a database study data that includes event data. Instead, Rienhoff teaches, in Paragraph 0044, on-line events archived for review by visitors to the web site but the data in the archived events is not stored in a database nor is it part of the study data. Indeed, the archived on-line events relate to genetics, various health issues, legal and ethical topics. Ignoring these aspects would read limitations out of the claim.

The proposed combination of Rienhoff and Fagan would produce archived on-line events in combination with a biomedical data warehouse with metadata for interrelating the data and user interface to capture data and metadata which at the protocol level describes patient identification, visit identifier information and study period (See, Fagan Paragraphs 0021 and 0030). Again, the combination of Rienhoff and Fagan does not teach storing in a database study data including event data. It is not surprising, therefore, that references do not mention the ability to track events and they do not enjoy this advantage.

As an additional example, the claimed invention as recited in the independent claims 1, 18, 34-37, 47 and 48, involves, limiting communication of messages between users to users having specific roles in connection with a specific study which, stated differently, restricts communication of messages between users based on their role in any particular study. For instance, a database that, among other things, maintains event data. More specifically, claim 1 recites this aspect as follows: “limit communication of electronic messages between users to those users having a specific role in connection with a specific study.” Claim 18 recites this aspect as follows: “limiting... communication of messages between users based on their role in any particular study.” Claim 34 recites this aspect as follows: “the role defines access

rights... wherein the delivery... of messages between users is restricted based on their associated roles.” Claim 35 recites this aspect as follows: “limit communication of electronic messages between users to those users having a specific role in connection with a specific study.” Claim 36 recites this aspect as follows: “limit communication of electronic messages between users having a specific role in connection with a specific study.” Claim 37 recites this aspect as follows: “limit communication of electronic messages between users those users having a specific role in connection with a specific study.” Claim 47 recites this aspect as follows: “limit communication of electronic messages between users those users having a specific role in connection with a specific study.” Lastly, claim 48 recites this aspect as follows: “imposing role-based restrictions on user access to clinical study data and on communications between users.”

The Examiner appears to misconstrue the teaching in Rienhoff by suggesting the Rienhoff teaches these features which it does not. First, a user in Rienhoff does not communicate with other users let alone via messages. The users merely visit the web site to view or submit data through it and, moreover, the databases in Rienhoff are not directly connected to the Internet for security reasons (See, e.g., Paragraph 0041). Second, the users in Rienhoff are given control in determining who may access their submitted information, which of the submitted information may be accessed and in what form the information is provided to others (See, e.g., Paragraph 0041). Restricting access to information the way Rienhoff is suggesting has nothing to do with limiting communications between users, and there is no mention of any role-based restriction. And, although Rienhoff teaches determining who has access to the information and in what form, it does not characterize the basis for letting a person have access or even suggest that access is role-based. In other words, unlike the claimed invention as recited in the aforementioned claims, Rienhoff does not teach or suggest limiting communications to users based on their role in the study.

The combination of Rienhoff and Fagan is likewise lacking these features. Fagan processes data requests using an analysis and reporting module and metadata to identify datasets that satisfy user requests (See, e.g., Paragraph 0026). Fagan makes no mention of the role-based restriction as described above. In other words, the proposed combination of Rienhoff and Fagan fails to teach or suggest limiting communications to users based on their role in the study.

The Examiner relies on Chou to make up for the deficiency in Rienhoff as to claim 47. However, even though Chou discloses three tiers, client, application and database, the server

application logic with the API (application programming interface), element 326 in Chou, is not the business logic in the application tier of the claimed invention. And, for obvious reasons, Chou does not teach the other features of the claimed invention as discussed above. Therefore, Chou does not make up for the deficiency in Rienhoff and, combined, these references do not produce the invention as recited in claim 47.

From these examples it is clear that the cited references, singly or combined do not teach each and every element of the claimed invention as recited in independent claims 1, 18, 34-37, 47 and 48.

Moreover, dependent claims 2-8, 11-25 and 28-33 are allowable for these as well as other reasons. For example, claims 2 and 19 recite that the “event data includes data of events that are scheduled events, unscheduled events, or both.” The Examiner alleges that, in paragraph 0044, “Rienhoff teaches the claimed ... data related to scheduled (=punctual)” (See, Section 8 at page 6 of the Office Action). However, the Examiner has apparently misread the claims and misunderstood the claimed invention, as well as Rienhoff’s description. Rienhoff is describing that, to build trust, online interview and interaction events need to be professional by being “punctual and well moderated” (Rienhoff paragraph 0044). There are no unscheduled events in Rienhoff and, in fact, there are no events of a clinical study or any study in Rienhoff. The on-line events are to instill trust in persons submitting their information rather than being part of a study. The only unscheduled actions in Rienhoff are unscheduled visits to the web site to look at archived on-line events data (See, Paragraph 0044), and these are not unscheduled events of a study, unlike the claimed invention.

In yet another example, claims 8 and 25 (and 34) recite roles associated with data access rights at a level of granularity that includes dataset definition level, data item definition level, or both. The Examiner relies on Paragraph 41 in Rienhoff in support of the proposition that Rienhoff teaches access rights at similar levels of granularity, but Applicants do not find a description of this feature in Rienhoff. There is no such thing in Rienhoff as dataset definition level, data item definition level, or both.

In addition to the foregoing Applicants note that the combination of the references is improper. For example, Chou is entirely unrelated to medical studies or systems for management of medical studies. A person of ordinary skill in the art would not look to Chou to solve the problem addressed by the present invention because it is so unrelated or impertinent to this

problem. To use Chou is tantamount to impermissible use of hindsight for composing the invention after having gleaned its details from Applicants disclosure.

Although the foregoing examples are not exhaustive, it is clear from these examples that the cited references do not support a *prima facie* case of obviousness of claims 1-8, 11-25 and 28-55. Because they are neither taught nor suggested by the cited references, claims 1-8, 11-25 and 28-55 are allowable over the cited references. Accordingly, Applicants respectfully request reconsideration and withdrawal of these claim rejections.

### III. CONCLUSION

In view of the foregoing, Applicants believe that the application is in condition for allowance and respectfully request a Notice of Allowance of claims 1-8, 11-25 and 28-55. Should any issue remain the Examiner is kindly invited to contact the undersigned attorney for a prompt resolution thereof.

The Commissioner is authorized to charge any fee deficiency or credit any fee overpay to Deposit Account 50-2778.

Respectfully submitted,

Date: September 29, 2005



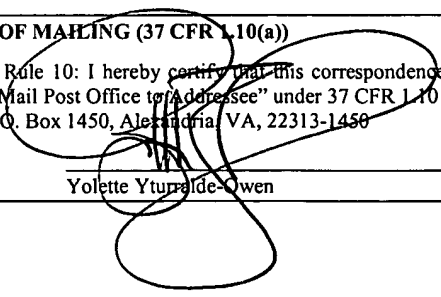
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CERTIFICATE OF MAILING BY "EXPRESS MAIL" - Rule 10: I hereby certify that this correspondence is being deposited on September 29, 2005 with the U.S. Postal Service "Express Mail Post Office to Addressee" under 37 CFR 1.10 as EL 989 609 571 US addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450

Date: September 29, 2005



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